NORMAN J. BLEARS (Bar No. 95600)
MICHAEL L. CHARLSON (Bar No. 122125)
HOGAN LOVELLS US LLP
525 University Avenue, 4th Floor
Palo Alto, California 94301
Telephone: + 1 (650) 463-4000
Facsimile: + 1 (650) 463-4199
norman.blears@hoganlovells.com
michael.charlson@hoganlovells.com

BENJAMIN T. DIGGS (Bar No. 245904)
HOGAN LOVELLS US LLP
Four Embarcadero Center, 22nd Floor
San Francisco, California 94111
Telephone: + 1 (415) 374-2300
Facsimile: + 1 (415) 374-2499
benjamin.diggs@hoganlovells.com

Attorneys for Defendants
VIVUS, INC., LELAND F. WILSON
and WESLEY W. DAY, Ph.D.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

MERLE KOVTUN, Individually and on Behalf of Others Similarly Situated,

Plaintiff,

v.

VIVUS, INC., LELAND F. WILSON, and WESLEY W. DAY, Ph.D.,

Defendants.

Case No. 4:10-CV-04957-PJH

REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS SECOND AMENDED CLASS ACTION COMPLAINT

Date: April 18, 2012
Time: 9:00 a.m.
Courtroom: 3 – 3rd Floor

The Honorable Phyllis J. Hamilton

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I. INTRODUCTION

As with his response to Defendants' initial motion to dismiss, Plaintiff opposes this motion largely by ignoring its points. Like his Second Amended Complaint (the "New Complaint"), the Opposition repeats general assertions about purported omissions based on after-the-fact summaries and fragments from the FDA Advisory Committee's July 15, 2010 hearing. He misses entirely that he needs *facts*, existing at the time of Defendants' supposed misstatements, that support a strong inference that Defendants' class-period statements were false or misleading when made, and that Defendants were at least deliberately reckless in not so recognizing. It is not enough to repeat most every question raised by a Committee member as if it reflected an established, serious side effect of Qnexa that was undisclosed but known to Defendants all along – particularly when the Committee record makes clear that many issues that Plaintiff posits as major safety concerns were not so viewed, and in some cases were not observed in the trials at all.

To plead securities fraud, Plaintiff must address, with specific factual allegations, two critical points. First, he must show that there was some clinically significant side effect apparent from the trial data that Defendants knew about when they spoke, but did not disclose. Despite access to the entire Advisory Committee record for 18 months now, Plaintiff points to none because there were none. Second, Plaintiff needs to plead specific facts that make it more plausible than alternative explanations that the side effects observed in the clinical trials, viewed in the context both of the known safety profiles of Qnexa's components and of the drug's efficacy data, were of a nature that Defendants, at the time they were making positive statements about Qnexa, in fact believed that those safety issues rendered the drug either not approvable or not saleable. Despite its substantial added heft, the New Complaint offers no new substance on these points. Nor does Plaintiff's Opposition offer any fresh perspective to explain his pleading deficiencies. Consequently, Defendants refer to, and renew, their arguments from both their opening papers and prior briefing, all of which apply equally here, as grounds for dismissal.

This time around, however, there is more. Were there any doubt about the inadequacy of Plaintiff's claims, it was put to rest on February 22, 2012, when the Advisory Committee met again to consider Qnexa, this time on a record that included a second year of trial data. After the

FDA stated in its briefing memorandum that the second year's data "was consistent with the safety profile" that VIVUS reported in its original New Drug Application ("NDA"), the Advisory Committee voted 20-2 to *recommend Qnexa for approval*. The issue now awaits FDA consideration. In contrast with Plaintiff's failure to offer facts showing their story of alleged fraud to be the "more plausible" explanation for the stock price decline, the February 2012 Committee vote vindicates Defendants' stated optimism about Qnexa and its prospects, and their commitment of tens of millions of dollars to the Qnexa clinical trials in the effort to gain approval for the drug. The 2012 action confirms the prior Committee vote to have been precisely what the record of the July 15, 2010 deliberations – read as a whole, rather than in snippets – shows: a cautious Advisory Committee, though seeing nothing alarming in the one-year data, wanted to confirm the drug's safety over a longer period given that many patients would likely remain on the drug for an extended time.

What happened on July 15, 2010 was the adverse resolution of a disclosed risk inherent in an investment in drug-development company like VIVUS. In his New Complaint, Plaintiff offers many more words. But in the end, he fails to allege anything beyond a negative vote by the Advisory Committee to support his conclusory assertion that the detailed Qnexa clinical trial data somehow contradicted Defendants' statements made during the alleged class period, much less that Defendants knew, or were deliberately reckless in not knowing, that the negative vote was, as Plaintiff terms it, "inevitable." The New Complaint comes nowhere close to meeting the stringent requirements for pleading securities fraud. It should be dismissed, with prejudice.

II. ADDITIONAL FACTUAL BACKGROUND

In its Complete Response Letter ("CRL") to VIVUS on October 28, 2010, the FDA asked VIVUS to submit the results of its year-long continuation trial of Qnexa ("SEQUEL") and to address two specific areas of interest: teratogenicity and cardiovascular risk. ¶ 239.[1] As described in the New Complaint, VIVUS re-submitted its NDA for FDA approval in the fall of 2011. *Id.* ¶ 241. On February 17, 2012, the FDA released its briefing document analyzing

[1] Despite Plaintiff's reference to it in the New Complaint, VIVUS has not included the CRL, a confidential document, in the record on this motion. If the Court considers it significant, VIVUS would be pleased to provide it with entry of an order permitting its submission under seal.

VIVUS's new submission, including the two-year data from the SEQUEL trial. *See* Reply Ex. 1.[2] Summarizing the safety data, the FDA stated that "[i]n general, safety data from the 52-week extension study, OB-305, was consistent with the safety profile noted in the 1-year safety cohort." *Id.* at 3; *see also id.* at 76 (same). On February 22, 2012, another Advisory Committee (the "2012 Committee"), including many of the same members as in July 2010, but as well as additional experts, met to consider Qnexa again. Reply Ex. 2. Recognizing that the strong safety data presented after one year remained consistent through a second year of use, the 2012 Committee voted overwhelmingly, 20-2, to recommend approval. Reply Exs. 3, 4.[3]

III. ARGUMENT

A. The New Complaint Does Not Comply with the Court's October 2011 Order

Plaintiff stands behind his technique of first quoting Defendants' public statements in full, and then pasting after nearly every sentence a selection from a stable of repeated "reasons" those statements are misleading or false. Plaintiff says he has met his obligation because the New Complaint purportedly describes why each statement was false and misleading "with exhaustive particularity" and contains "a mountain of detailed factual information." Opp. at 6. While the New Complaint is indeed mountainous and exhausting, it satisfies neither the Court's October 13, 2011 Order nor the exacting pleading standards applicable to Plaintiff's case.

Plaintiff mistakes mind-numbing repetition for factual particularity, in his New Complaint even more than in his prior effort. Breaking out each Defendant disclosure sentence by sentence and adding dozens of pages to the New Complaint means nothing when the "reasons" for falsity that comprise Plaintiff's mantra are either (1) not facts, but are instead later-expressed opinions or concerns of Committee members (*see, e.g.* ¶¶ 57(b)(i), (iii) (vi), (ix)); or (2) facts that were either disclosed by Defendants early in the class period and/or constitute additional detail consistent

[2] *See* Supplemental Request for Judicial Notice in Support of Motion to Dismiss Second Amended Complaint ("Reply RJN") and accompanying exhibits. Numbered exhibits to the Reply RJN are referred to as "Reply Ex._," while "Ex._" refers to lettered exhibits to the Diggs Declaration filed with Defendants' opening brief, the ("Mot."). All references to "¶" are to the New Complaint unless otherwise indicated.

[3] The 2012 Committee included 12 members who had participated in the July 2010 Advisory Committee, including 7 who previously voted against approval. Six of those 7 voted for approval at the February 2012 Committee meeting.

with Defendants' disclosures (*see, e.g.* ¶¶ 57(b)(iii), (iv), (vii), (viii)).[4] Plaintiff has not complied with the Court's October 13 Order to provide a clear and comprehensible account of which Defendant statements are false and misleading and what specific facts support that grave assertion.

Plaintiff primarily relies on incomplete summaries of *opinions* of Advisory Committee members and attempts to pass them off as *facts*. But even if the opinions were facts, Plaintiff fails to explain how they demonstrate that Defendants' many quoted statements were false or misleading when made. Plaintiff still leaves it to Defendants and the Court to provide the logical and factual linkage between the quoted statements and his grab-bag of "reasons" – a matching exercise that Plaintiffs' swollen New Complaint has complicated further. As the Ninth Circuit explained even before the Private Securities Litigation Reform Act, a complaint does not plead fraud with specificity where it alleges merely that "defendant said A whereas the true fact is B." Unless a plaintiff *explains why* A and B are supposed to be inconsistent with one another, he has not adequately pled fraud. *Glenfed, Inc. Sec. Litig.*, 42 F.3d 1541, 1553 n.11 (9th Cir. 1994). Plaintiff must allege with specificity *why* and *how* the alleged misstatements are false. *Marolda v. Symantec Corp.*, 672 F. Supp. 2d 992, 1000-01 (N.D. Cal. 2009). He comes nowhere close.

Eschewing his burden under Rule 9(b) and the PSLRA, Plaintiff says he need not plead "evidence" or "specific factual details not ascertainable in advance of discovery." Opp. at 6, quoting *Gibson v. United States*, 781 F.2d 1334, 1340 (9th Cir. 1986). That pre-PSLRA, pre-*Iqbal* and *Twombly*, *civil rights* case does not mention Rule 9(b) and has no relevance to the insufficiency of Plaintiff's pleading here. Specific facts are *exactly* what the securities fraud pleading standards require; and the public record from which those facts might be drawn, if they existed, is extensive in this case.[5] That Plaintiff cannot provide that factual information, but

[4] As Defendants have discussed before, the conclusion that the facts disclosed in the complete FDA briefing were consistent with, not contradictory to, Defendants' prior statements is evident not only from a plain comparison, but also from the substantial positive reaction to public release of the detailed data, including a 17% increase in VIVUS's stock price on June 13, 2010. Had there been some "bombshell" in the data that contradicted earlier optimistic statements, the markets would have reacted in precisely the opposite way. *See infra* at Part III.C.1.

[5] What factual information Plaintiff claims to provide underscores, rather than refutes, the New Complaint's deficiencies. Plaintiff says the "mountain of detailed factual information" includes "the substance of the Summary Minutes, Vivus's decision to conduct another fetal outcome study, and the problems with combining phentermine and topiramate." But he fails to allege how a brief

instead disclaims the need to do so, speaks volumes.

B. The Advisory Committee's Lopsided February 22, 2012 Vote Recommending Approval Shows the Fallacy of Plaintiff's Claims

As noted, the FDA Advisory Committee reconsidered Qnexa on February 22, 2012, and voted overwhelmingly to recommend approval. Through two motions to dismiss, Defendants have contended that many members of the July 15, 2010 Advisory Committee who voted against approval did so *not* because of issues with the data gathered to that point, but out of a desire to *confirm* that those data held up over time. *See, e.g.* Mot. at 9. Plaintiff responds that Defendants "knew or should have known that the [approval] effort was doomed to failure based on the outcome of the clinical studies." Opp. at 25 n.24. That dispute has now been decisively resolved. The two-year data demonstrated a safety profile consistent with data gathered over one year (*see* Reply Ex. 1 at 3, 76) and confirmed the safety profile of Qnexa that Defendants reported on the first day of the alleged class period. Ex. B. The recent lopsided vote for approval shows that many Committee members who first voted against approval needed precisely what they said in July 2010 – to see the safety profile reflected in the Phase 3 trial data to that point sustained over a longer period. *E.g.*, Ex. G at 354 ("I think we need more data"), 361 ("we just need longer term data"). That fact sinks Plaintiff's argument that Qnexa's demonstrated side effects "doomed" any prospect of a favorable Committee vote, and that Defendants knew that when they made positive statements about Qnexa's safety. Without that argument, Plaintiff's entire fraud claim dissolves.

Plaintiff will no doubt say that the 2012 vote, coming after the alleged class period, is irrelevant.[6] But Plaintiff's theory of fraud is that Qnexa's safety data, which Defendants knew about but purportedly did not disclose, was so bad that Defendants knew Qnexa "could not and would not be approved." Opp. at 4; ¶¶ 54-203. Over and over Plaintiff alleges that "the Phase 3

summary of some opinions expressed in 372 pages of transcript at the Advisory Committee or an October 2011 announcement of a follow-up study shows the much earlier statements by to have been false when made. Nor does he plead facts – beyond his own say-so – suggesting new issues specific to combining Qnexa's two component drugs. *See* Mot. at 15-16; *infra* at Part III.C.3. Despite the Court's clear directive, Plaintiff still leaves it to Defendants and the Court to guess 1) *what* facts support Plaintiff's allegations and (2) *how* those supposed facts might support his claims of fraud.

[6] Of course, Plaintiff has no trouble relying on post-class period developments where he thinks they *help* his case. *See, e.g.* ¶¶ 238-41 (detailing post-class period analyst reports, the FDA's October 2010 denial of VIVUS's NDA, and VIVUS's 2011 resubmission of that NDA).

Trials showed significant, potentially serious and life-threatening adverse effects of the type that scuttled approval for other obesity drugs" and that "fact" made every Defendant statement false. Defendants have noted that what Plaintiff characterizes as problems that the clinical data "showed" were in fact cited by Committee members as *potential* issues. *See, e.g.*, Mot. at 13 n.6; Ex. G at 151, 304, 320, 350, 367; *see also id.* at 53 (only death in the Phase 3 trials was a patient in one study's placebo arm). The 2012 Committee vote confirms Defendants' position and resolves those "potential" issues in favor of approval in nearly every member's mind. The 2012 Committee vote is relevant because it points up the problem with Plaintiff's reliance on out-of-context, incomplete citation to Committee members' opinions and expressions of concern, rather than facts. The facts – that is, the Qnexa safety profile demonstrated by Phase 3 data – have not changed; but with confirmation of those data over a longer time, the Committee's conclusions have, and the vote outcome is very different. Plaintiff's house of cards has collapsed.[7]

C. Plaintiff Fails to Allege Facts Showing That Defendants' Statements About Safety Data from the Qnexa Trials Were Materially False or Misleading

1. The market reaction supports Defendants' statements.

Plaintiff cannot dispute that both the VIVUS and FDA briefing documents analyzing the Qnexa trial data were publicly released on July 13, 2010. His claim that previously undisclosed negative data contradicted Defendants' prior positive statements is undermined by the fact that when the detailed Qnexa data and analysis were disclosed, two days before the Committee meeting, VIVUS's stock price jumped dramatically. The market, awaiting these materials, understood that the data confirmed what the Company had previously said; and investors voted their dollars accordingly. As we have explained before, this fact is a death knell to Plaintiff's claims; not surprisingly, his attempt to square it with his own imagined story of fraud conflicts with both his own allegations and the judicially noticeable record.

[7] Plaintiff may argue that Defendants knew Qnexa's demonstrated safety data meant Qnexa would not be recommended for approval after *one year*, but might be after two years, and therein lies the fraud. Beyond that Plaintiff alleges no facts to support that parsing interpretation, the conclusion conflicts with the fact the Phase 3 trial design and endpoints were cleared with the FDA under a Special Protocol Assessment ("SPA") and the fact that the FDA's Guidance for Industry states "a reasonable estimation of the safety of a weight-management product upon which to base approval generally can be made … [after] 1 year of treatment." Ex. D. at 246.

Plaintiff again hypothesizes that "investors needed the expert guidance and comments from the FDA Panel to fully digest and comprehend the true meaning of the voluminous safety data." Opp. at 18. This directly contravenes Plaintiff's efficient-market allegations, (¶¶ 34-35) – allegations necessary to support Plaintiff's invocation of a "fraud-on-the-market" theory of reliance. *See In re Bare Escentuals, Inc. Sec. Litig.*, 745 F. Supp. 2d 1052, 1074 (N.D. Cal. 2010). Plaintiff cannot have it both ways, at once alleging that "the market for Vivus securities *rapidly absorbed all publicly material information* regarding Vivus and that information was reflected in the price of Vivus securities" (¶ 35), but then claiming that "the market took two days to process the significance of these analyses and the underlying data" (Opp. at 18). Plaintiff notes that the briefing documents with exhibits ran 555 pages. Opp. at 18. But all of the key safety "revelations" upon which his fraud theory appears to rely – the "double rate of depression," the "four times as many cognitive adverse effects," the "increased heart rate" and so forth – are summarized within the *first seven pages* of the FDA Memo. *See* Ex. J at 3-7. In any event, the fallacy of Plaintiff's version of market-efficiency theory is underscored by the fact that VIVUS's stock *was* responsive: on July 13 when the data came out, the stock posted its largest one-day gain since September 2009.[8] The July 13 FDA release and price reaction contradict Plaintiff's assertion that "[t]he deception finally unraveled on July 15, 2010" (Opp. at 4); the only thing that happened on July 15 was the Advisory Committee vote.[9] There can be no real dispute under Plaintiff's own efficient-market allegations: the market evaluated the information released on July 13 and made its own positive determination. That fact negates Plaintiff's assertion that

[8] Plaintiff's reliance on the *No. 84 Employer-Teamster* and *Gilead* cases is misplaced. Opp. at 18. In those cases, the share-price decline was delayed either by revelation of previously undisclosed information or by a continuing misrepresentation. *See In re Gilead Sciences Sec. Litig.*, 536 F.3d 1049, 1054 (9th Cir. 2008) (impact of off-label marketing and FDA Warning Letter about it revealed only later, when Gilead released its quarterly financial results showing disappointing sales of the subject drug); *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. West Holding Corp.*, 320 F.3d 920, 935 (9th Cir. 2003) (price response delayed because America West continued to reassure analysts that compliance with the subject settlement agreement would have no noticeable economic effect on the company). Nothing analogous is alleged here.

[9] Plaintiff claims that by not arguing loss causation as a specific ground for dismissal on this motion, Defendants "conceded that the report of the vote of the FDA Panel…did, indeed, reveal the truth of Defendants' prior misrepresentations and omissions to the market," causing loss to Class Members. Opp. 18 at n.15. Of course, Defendants concede nothing of the sort.

VIVUS's earlier optimistic statements about Qnexa's prospects were false or misleading.[10]

2. The Committee's discussion shows a close vote, not fraud.

Plaintiff says that Defendants made statements "which led investors to believe that FDA approval of Qnexa was all but assured" while in possession of data that, when it became public, meant "Qnexa could not and would not be approved by the FDA based on existing safety data". Opp. at 4. That all-or-nothing theory discounts not only the market's ability to interpret the data as noted above, but also the expertise and judgment of the Committee members who voted to recommend approval in July 2010. Plaintiff's claim that the Committee's negative vote was "inevitabl[e]" (*id*. at 2) cannot be squared with, for example, Dr. Hendricks's feeling that VIVUS "did an outstanding job producing the data, and that the data does show … that the drug is reasonably safe and that we should approve it." Ex. G at 364. How could Defendants' statements to the same end be fraudulent? Neither the New Complaint nor the Opposition explains this basic inconsistency: if the clinical data plainly contradicted Defendants' statements about Qnexa's approval prospects, how could six Committee experts have recommended approval (and much of the investing public concluded approval was likely)? *Cf.* ¶ 238 (citing news article calling Committee result a "surprise vote"). The answer, of course, is that those voting for approval did not miss some land mine in the data; they merely judged the data and the balancing of risks differently from those who wanted a longer look. This rebuts a claim of fraud.

The *AstraZeneca* case involved similar claims – that AstraZeneca misrepresented the safety and potential approvability of its trial drug, Exanta. *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 456 (S.D.N.Y. 2008). There, plaintiffs alleged that when the FDA briefing was

[10] Plaintiff's attempt to parse the language of two July 13, 2010 articles reporting on the release of the FDA analysis is as unavailing as his attempt to avoid the consequences of his efficient-market allegations. *See* Opp. at 18. First, his assertion that the market reacted only to the "tone" of the FDA Memo and not to any safety information is belied by the article Plaintiff quotes. That article states, among other things, that "[t]he FDA review focuses mainly on the drug's safety, notably the potential for birth defects, psychiatric and cognitive side effects, …metabolic acidosis, and cardiovascular risks." Ex. F at 1 (also noting other side effects and stating the "panel may be reluctant to recommend approval with the safety risks"). To suggest that investors received only data on efficacy and not safety is just wrong. *See also* Exs. AA, BB. Second, Plaintiff's efforts to explain away these *particular* articles miss the point. The *data and the FDA's analysis of it were public* and, together with these and other media and analyst reports on all sides, were reflected in the market price for VIVUS stock, which rose 17%.

released days before the advisory committee meeting, AstraZeneca stock dropped 6%, and at least one analyst stated that the FDA briefing revealed new safety issues not previously disclosed. *Id.* at 462-63. Shortly thereafter, plaintiffs claimed, an advisory committee voted 11-1 against recommending approval, and AstraZeneca was lambasted in the media for concealing the extent of Exanta's safety issues. *Id.* at 463. Even so, after reviewing the FDA and company briefings to the advisory committee, the court found no knowingly false or misleading statements. "It is impossible to read the FDA document and the AstraZeneca document without concluding that both present the honest analysis and conclusions of their authors." *Id.* at 471. The vote against approval, even at 11-1, "does not mean that [the sponsor] was not conscientious in advocating the drug [] before the FDA, nor does it mean that the information issued publicly over the course of more than a year was dishonest or recklessly disseminated." *Id.*

The logic of *AstraZeneca* applies even more forcefully here, where: (1) VIVUS's stock price rose sharply upon release of the FDA briefing materials; (2) Plaintiff alleges no contemporaneous public or media reaction suggesting the briefing materials disclosed previously unknown risks; (3) the Committee voted 10-6, with the Committee chair stating that "the committee seems to be closer than perhaps appears…." (Ex. G. at 351); and more recently, (4) an expanded Advisory Committee reconvened and voted overwhelmingly to recommend approval once an additional year's data substantially confirmed the safety data initially presented. Nothing in the New Complaint transforms this debate between honestly held positions into a tale of fraud and deception. Mot. at 12-13; *see also Padnes v. Scios Nova, Inc.*, 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001).

3. Plaintiff ignores the context of Defendants' statements and mischaracterizes the *Matrixx* decision.

Despite the close July 2010 vote by a divided panel, Plaintiff asserts that certain Committee members' desire to see longer-term safety data reflected a "consensus as to the inadequacy of Qnexa's safety data" from its year-long Phase 3 trials. Opp. at 14. Like his contention that the safety data made a negative Committee vote "inevitable," the record belies this assertion as well. Yes, some Committee members, like Dr. Proschan, said that "I think if we had

had longer follow-up, I probably would have voted [for approval]. But I just don't feel comfortable with one year follow-up." Mot. at 11; Ex. G at 351. But lack of data about longer-term safety does not equate to a *demonstrated* lack of long-term safety – as the additional year of data that VIVUS submitted with its renewed NDA shows. Plaintiff cites no findings to undermine the truth of Defendants' statements about the results observed in the one-year trials, a period selected based on the FDA's Guidance for Industry and approved in SPAs. *See* Mot. at 12. Nor were calls by some Committee members for longer-term data based on a stated view that *observed* safety issues precluded approval. Instead, they expressed concern about *potential* safety issues (known to be issues with Qnexa's components) and a desire to ensure that those issues did not present themselves as serious after prolonged use of the drug. *Id*. at 10 n.3. As discussed, the 2012 Committee vote reflects that that desire was satisfied by the two-year data.

Plaintiff's efforts to equate this case with others actually involving material omissions of negative trial data again underscore what is missing from the New Complaint. In several cases Plaintiff cites, courts found fraud adequately pled where defendants continued to assure the public of strong trial results when underlying data allegedly known to them revealed no observable difference between outcomes on the drug and placebo arms, and no basis for believing the drugs were at all effective. *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1020 (S.D. Cal. 2005), *In re Nuvelo Inc. Sec. Litig.*, 668 F. Supp. 2d 1217, 1222 (N.D. Cal. 2009), and *Warshaw v. Xoma Comp.*, 74 F.3d 955, 960 (9th Cir. 1996). That could not be more different from the situation here, where efficacy is unchallenged. Instead, Plaintiff's focus is on supposed nondisclosure of additional (but less severe) adverse events beyond the top-line data VIVUS released at the start of the class period. *See Heywood v. Cell Therapeutics, Inc.*, 2006 WL 5701625, at *6 (W.D. Wash. May 4, 2006) (dismissing case and distinguishing *Immune Response* and *In re Amylin Therapeutics, Inc. Sec. Litig.*, 2003 WL 21500525 (S.D. Cal. May 1, 2003), as instances where "defendants either grossly misrepresented some specific material fact, or failed to disclose some concrete indication that they could not expect FDA approval"). Plaintiff does not, and cannot, point to any similarly negative data withheld from the market. *In re Merck & Co., Inc. Sec., Deriv. & ERISA Litig.*, 2011 WL 3444199 (D.N.J. Aug. 8, 2011), on which Plaintiff

relies, is another case in point. In sustaining the complaint there, the court identified specific internal e-mails acknowledging the problems defendants publicly claimed did not exist and discussing how to avoid disclosing them, as well as documents showing that defendants disbelieved the hypotheses they proposed publicly. *Id*. at *11-12, 14. Here, by contrast, Plaintiff points at most to some additional mild side-effect events, later-voiced Committee member concerns, and vague and undated confidential witness assertions. The difference is dramatic.

As forecast in Defendants' opening papers, Plaintiff relies on *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), asserting that some adverse events must be disclosed even if not statistically significant. *See* Mot. at 17; Opp. at 17.[11] Plaintiff offered this same overreading of *Matrixx* in opposition to Defendants' prior motion. Prior Opp. at 8-11. And as we responded the last time, nothing in *Matrixx* suggests that VIVUS's top-line safety disclosures were inadequate. Prior Reply at 6-9. In *Matrixx*, the issuer elected not to disclose reports of adverse side effects of its over-the-counter cold remedy *not* because it believed they were meaningless "but because it understood their likely effect on the market." 131 S. Ct. at 1324–25. Nothing alleged in the New Complaint suggests that was the case here, and the "effect on the market" when complete data were disclosed confirms it was not. *Accord Philco Invs. v. Martin*, 2011 WL 500694, at * 7-8 (N.D. Cal. Feb. 9, 2011) (release of top-line trial results for Alzheimer's drug not rendered misleading because it did not include all information later released or because plaintiffs disagreed with defendants about data's importance); *see also Philco Invs. v. Martin*, 2011 WL 4595247, at *7 n.11 (distinguishing *Matrixx* and dismissing amended complaint with prejudice).

The fact is that *Matrixx* reinforces a point that VIVUS has urged and that Plaintiff continues to ignore – *context matters*. The context that Plaintiff disregards is the extensive, well-documented history of Qnexa's two component drugs, phentermine and topiramate – drugs that have been approved for decades and that have been prescribed to literally millions of patients at

[11] Plaintiff makes the bizarre argument that Defendants somehow equate the "avalanche of information" *Matrixx* says need *not* be disclosed with the *length* of Plaintiff's New Complaint. Opp. at 9 n.9. That nonsensical contention aside, *Matrixx* does undercut Plaintiff's claim that Defendants misled the market by disclosing serious and moderate adverse events regarding, for example, psychological and cognitive data without simultaneously presenting *all* of the safety data, including the large number of mild adverse events observed. *See* 131 S.Ct. at 1318.

much higher doses than in Qnexa. Mot. at 14-15. That context was known and understood by the FDA, by the Advisory Committee *and by the markets*. *Id.* And VIVUS *specifically disclosed* risks relating to the known side effects of these components, *e.g.*, Ex. P at 36-39, including many of the very risks that Plaintiff says VIVUS hid, *cf.* ¶ 57(a)(i) (potential for cognitive and psychological side effects); 57(b)(i) (longer-term studies potentially required).

When VIVUS disclosed that the Qnexa trials showed "nothing unexpected," it was understood that the baseline expectations were established by the component drugs – a point repeatedly emphasized in the statements Plaintiff challenges. *See, e.g.*, ¶¶ 70, 150. In his Opposition, Plaintiff adheres to his unsupported assertions that the combination of the drugs "increased the known risks and magnitude of the side effects beyond those associated with each component individually and/or was creating new, potentially serious side effects." Opp. at 15-16, 10 n.10. But as noted in our opening papers, this assertion is made without reference to any data, Committee member comment, media analysis or other factual underpinning. Mot. at 15. Plaintiff has just invented these assertions for his New Complaint; he offers no facts to support his insinuation that Defendants' statements about the consistency of the Qnexa safety profile with that of its components was in any sense false or misleading. His only response now is that he is "not required to plead evidence." Opp. at 16 n.14. Once again, Plaintiff ignores his substantial pleading burden, and he confuses evidence with the specific fact-based allegations that absolutely *are* required under applicable pleading rules.

4. Defendants' statements about trial results related to specific potential side effects were truthful.

Defendants will not repeat the detailed arguments regarding Plaintiff's various safety-related assertions from their opening brief and prior briefing as Plaintiff's basic assertions about these matters are unchanged. Mot. at 14-21. *See also* Prior Mot. at 14-21; Prior Reply at 9-14. However, a few comments in response to the Opposition are in order to demonstrate the lengths to which Plaintiff goes to concoct a fraud.

Psychiatric Results. Plaintiff says Defendants' statements about psychiatric events in the Phase 3 trials were misleading because they "repeatedly affirmatively reiterate[ed] the absence of

any data signaling a suicide risk," and "omitt[ed] any mention of data in their possession showing depression among patients." Opp. at 6; *see also id.* at 1. But even Plaintiff recognizes that the FDA Committee members noted "the absence of a clear signal for suicide risk." Opp. at 7 (quoting Dr. Rogawski – who voted for approval – that "we didn't pick up an increase in suicidality risk"). Given the data, which Plaintiff does not challenge, it was entirely accurate for Defendants to note the absence of a signal for suicide. *Accord* Reply Ex. 1 at 3 ("no reported adverse events regarding suicidality in the 2-year safety cohort"). While he repeats the word "suicide" over and over in both his New Complaint and Opposition, Plaintiff pleads no facts to contradict the no-signal conclusion.

His assertion that Defendants omitted "any mention" of depression data is flatly untrue. VIVUS disclosed data for moderate and severe depression-related adverse events, as well as for depression-related study discontinuations, on Day 1 of the class period. Ex. L at slides 29-30. Plaintiff does not suggest the reports were inaccurate; but he says that VIVUS should also have disclosed data about *mild* depression events because the differential incidence of events between top-dose and placebo patients was wider with mild events (the majority of events) included.[12]

Plaintiff does not plead facts suggesting that disclosure of mild events mattered. He asserts, however, that it is "undeniable" that "had investors been aware of the true extent of the adverse indications," they would have paid less for VIVUS shares, citing cases saying that securities are accurately valued where negative study results are available to the market. *See* Opp. at 8. But the judicially noticeable facts show precisely the opposite. In reality, when the so-called "true extent" of the psychiatric adverse events was made public in the briefing documents released before the Advisory Committee meeting, VIVUS's stock price *rose*, and analysts noted the "low" level of psychiatric side effects (Ex. F at ¶ 3). *See supra* Part III.C.1. Moreover, contrary to Plaintiff's claim that Defendants falsely implied depression concerns "presented no risk to FDA approval," (Opp. at 8), VIVUS in fact made specific risk disclosures that the psychiatric side effects observed in Qnexa's components, as well as the shadow cast by adverse

[12] The FDA's briefing document defines a mild event as one which "[d]oes not interfere with the subject's usual function." Ex. J at 80.

effects of other weight-loss drugs, could negatively affect Qnexa's approval chances. *E.g.*, Ex. P at 36-39. Finally, despite Plaintiff's table-banging about the purportedly pervasive incidence of adverse psychiatric side effects, it is notable that Plaintiff does not allege psychiatric issues as a reason listed by FDA for disapproval in its October 2010 CRL (and they were not). ¶ 239.

Cognitive Results. Plaintiff also does not and cannot allege that cognitive issues were cited in the CRL as a reason for initial disapproval of Qnexa (again, they were not). ¶ 239. Even the analyst quoted in the New Complaint stated that most of the Committee was unconcerned with cognitive issues. Mot. at 19; ¶ 235. Yet because the 2010 vote was ultimately negative, Plaintiff cries fraud here as well. The claim is that Defendants said early in the class period, based on expert analysis, that there was "no clinically significant change in overall cognitive function." Opp. at 9. They said it again in their detailed briefing to the FDA. Ex. D at 121. But the FDA Memo reflects no disagreement. Ex. J at 5. Market analysts, the FDA reviewer, and Committee members all noted that the observed cognitive effects were known side effects of topiramate. *E.g.*, ¶ 235, Ex. G at 138, 299. Those effects were covered in VIVUS's risk disclosures. *E.g.*, Exs. O at 62, P at 37. Yet Plaintiff says the public was tricked.

Once more, Plaintiff fails to identify anything in the trial data that contradicted public statements, but only points to additional, mild adverse events (that did not change VIVUS's conclusions when presenting the data to the FDA) and calls on *Matrixx* for salvation. But again, nothing in *Matrixx* implies that *every* adverse effect must be disclosed; indeed, it holds the opposite. 131 S. Ct. at 1321; *see also* Mot. at 17-18.

Cardiovascular Results. Plaintiff's claims about cardiovascular safety results turn on two issues that received almost no mention in the Committee's discussion: the withdrawal of the drug combination fen-phen from the market, and potassium. Opp. at 10-11. The FDA Memo disposed of the fen-phen issue by simply repeating its conclusion, reached after research following the fen-phen situation of 12 years before, that the phentermine component of that product was *not* the cause of fen-phen's cardiovascular side-effects. Ex. J at 15, 63. Nothing in the Advisory Committee record suggests that fen-phen was the reason for the negative vote in July 2010; but even if it were, VIVUS's risk disclosures throughout the class period disclosed the

threat that fen-phen posed to possible approval of Qnexa.[13] Investors were not misled.

Nor were the Qnexa trial data showing a slight increase in heart rate among trial subjects a surprise, as Plaintiff asserts. Opp. at 11. In fact, the one beat-per-minute average increase in heart rate was disclosed in briefings the third day of the class period. ¶ 75. (Although he quotes Dr. Day's September 11, 2009 statement, Plaintiff appears to be talking about precisely this increase where he refers to "the undisclosed increased heart-rate signal." *Id.* at 10.) To contradict Dr. Day's conclusion that the increase was not of clinical concern, Plaintiff makes assertions about potassium that are neither supported nor linked to the Phase 3 trial data. Yes, the Committee briefing documents included data on decreased potassium levels (a known side effect of topiramate (¶ 262)); but the Committee never so much as mentioned potassium. Mot. at 21.[14]

Plaintiff also says that certain Committee members' concerns about cardiovascular safety did more than "evidenc[e] simply the desire for more research." Opp. at 10. Yet after another year of data that, according to the FDA, showed the same slight increase in average heart rate, the Committee voted almost unanimously to recommend approval. Reply Ex. 1 at 3. *Cf. Construction Laborers Pension Trust of Greater St. Louis v. Neurocrine Biosciences, Inc.*, 2008 WL 2053733 at *7 (S.D. Cal. May 13, 2008) (though FDA requested further data analysis, the data provided met FDA approval guidelines, which "tends to negate the inference defendants

[13] *See, e.g.*, Ex. P at 36, from risk subsection *headlined* "Association with fen-phen could lead to increased scrutiny of our investigational product candidate, Qnexa": "Moreover, the adverse clinical history of fen-phen and dexfen-phen combinations for obesity may result in increased FDA regulatory scrutiny of the safety or the risk/benefit profile of Qnexa and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or ultimately market acceptance if Qnexa is approved for commercial sale." *See also* Ex. O at 61; Ex. Q at 63-64. Plaintiff ignores these disclosures when he asserts, without factual support, that "Defendants … either knew, or recklessly ignored" this potential scrutiny. Opp. at 10.

[14] In our opening brief, we pointed to numerous inconsistencies in Plaintiff's story of supposedly illicit potassium supplementation in a Phase 1 trial (but not in the Phase 3 trials). Mot. at 21, 28. Plaintiff's Opposition makes no attempt to respond to or clarify the issue, simply repeating the New Complaint's allegations. Opp. at 11. Even accepting Plaintiff's uncorroborated CW allegations as to the Phase 1 trial as true (they are not), Plaintiff offers nothing to connect the allegations to: (1) the Phase 3 results generally; (2) reduction in blood pressure generally (beyond noting "*some* evidence, *although not universally accepted*, that potassium supplementation *might* cause a slight drop in blood pressure" (¶ 263) (emphasis added)); (3) reduction in blood pressure among Phase 3 trial patients specifically; or (4) any other measured results relevant to cardiovascular data. Plaintiff fails to explain how this story even makes sense, let alone supports his fraud allegations.

knew the FDA would not approve the Application").

Teratogenicity and Metabolic Acidosis Results. Nowhere in the New Complaint's exhaustive litany of supposedly false statements does Plaintiff allege any statement about teratogenicity, save Defendants' repeated *risk disclosures* explaining that pregnant women were ineligible for the Phase 3 trials and that Qnexa would have a label "warning against use by women who are or are considering becoming pregnant." ¶ 198; *see also* Exs. O at 62, P at 38, Q at 65, C at 10. No statements about C labels or X labels are pled, nor are facts alleged to show Defendants said one thing publicly but believed something else about risk of fetal harm. Indeed, the only Defendant reference to Category C in the record – never mentioned by Plaintiff – is the description of Qnexa's *component* drugs in VIVUS's briefing document, released publicly on July 13, 2010.[15] Plaintiff simply alleges no false or misleading statement about teratogenicity.[16]

5. Defendants' risk disclosures belie Plaintiff's claims of deception.

VIVUS's extensive risk disclosures included detailed cautions that specifically addressed the very issues about which Plaintiff now complains. Mot. at 23-24. The complained-of press releases disclosed myriad risks associated with Qnexa's development, approval and marketability, and referred the reader to SEC filings that brim over with risk factors. *Id*. VIVUS's statements about the future of Qnexa and of the Company were protected under the safe harbor and bespeaks caution doctrines, Plaintiff's stock objections notwithstanding. *See In re Bare Escentuals, Inc. Sec. Litig.*, 745 F. Supp. 2d 1052, 1080 (N.D. Cal. 2010). Those statements were identified as forward-looking and were accompanied by meaningful cautionary language; and Plaintiff alleges no facts to support an inference that they were made with actual knowledge of falsity (let alone a strong inference as cogent and compelling as other, non-culpable explanations). *See* 15 U.S.C. §

[15] Plaintiff notes topiramate was changed to Category D in 2011 and implies VIVUS advocated a label for Qnexa less restrictive than that of its components. Opp. at 12 n.11. Putting aside Plaintiff's failure to point to *any* VIVUS statement about pregnancy categories or any fact to support their suggestion, there can be no doubt that both components were Category C at the time of VIVUS's NDA. *E.g.*, Ex. D. at 17.

[16] After two complaints totaling some 250 pages and two briefs of 60 pages more, Plaintiff has yet to reference any Defendant statement on metabolic acidosis or to mention the topic in his briefs in any way (beyond section headings). Mot. at 21; Prior Reply at 14. Enough said.

78u-5(c).[17] *See also* Mot. at 25-30; *infra* Part III.D.

The pages of risk disclosures included in every one of VIVUS's quarterly filings, *e.g.*, Exs. P at 31-78; Q at 59-97, directly contradict Plaintiff's allegations that material information was withheld from investors. *See* ¶¶ 184-203. The risks that resolved negatively on July 15, 2010 were disclosed in detail. *See, e.g.*, Exs. O at 59-63, P at 31-39, 43, Q at 59-66.

6. Statements of general optimism and opinion are not actionable

Finally, as with the previous motion to dismiss, Plaintiff makes no effort to distinguish the cases holding that general statements of opinion and optimism do not support a securities fraud claim. Mot at 22-23 (citing cases). At most, he makes the general point that optimistic statements may be actionable if defendants fail to disclose material risks that undercut them or that opinions may be actionable if they are knowingly untrue or made without reasonable basis. Opp. at 14 (citing *Virginia Bankshares v. Sandberg*, 501 U.S. 1083 1093-94 (1991); *Amylin*, 2003 WL 21500525, at *5). As we have explained, Plaintiff does not allege specific facts to support either situation. *See, e.g.*, *Yourish v. California Amplifier*, 191 F.3d 983, 997 (9th Cir. 1999) ("clearly insufficient" for plaintiffs to say that a "later, sobering revelation" makes "an earlier, cheerier statement a falsehood."); Mot. at 23. Neither Plaintiff's cases nor any fact alleged in the New Complaint explain how statements that, for example, Qnexa has an "excellent" or "compelling" risk/benefit profile (*e.g.*, ¶¶ 55(a), 69(b)), or that trials have shown "remarkable" safety and efficacy (*e.g.*, ¶ 57(d)) could be actionable. *Glen Holly Entm't Inc. v. Tektronix, Inc.*, 352 F.3d 367, 379 (9th Cir. 2003); *Philco*, 2011 WL 500694, at *6.

D. Plaintiff Fails to Allege A Strong Inference of Scienter

Plaintiff says a conclusion that VIVUS's statements about Qnexa were accurate and reasonable is possible only by ignoring the collective approach to scienter required by *Matrixx*

[17] Plaintiff says that some statements involved present facts. Opp. at 29. But "even a statement of present fact may become a forward-looking statement if a plaintiff's sole allegation of falsity is based on the existence of some future risk of failure." *In re Discovery Labs. Sec. Litig.*, 2006 WL 3227767, at *15 (E.D. Pa. Nov. 1, 2006). Furthermore, alleged omission of an historical fact does not change the analysis because "when the factors underlying a projection … include both assumptions and statements of known fact, and a plaintiff alleges a material fact is missing, the entire list of factors is treated as a forward-looking statement." *In re Avon Prods., Inc. Sec. Litig.*, 2009 WL 848017, at *17 (S.D.N.Y. Feb. 23, 2009).

and *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). Opp. at 20. He says that "Defendants cannot demonstrate … that an inference of non-fraudulent intent is more plausible than the competing inference of fraud." *Id*. at 19-20. But it is *Plaintiff* who has the burden to plead scienter sufficiently and that an inference of fraud is the more plausible one to draw from the facts alleged. It is he who has failed to carry that burden. Notwithstanding, Defendants *have* in fact shown non-fraudulent intent to be far more plausible. *Tellabs*, 551 U.S. at 323. By any fair reading of the record, the alleged misstatements, viewed in light of *all* facts alleged and in the public domain, tell a story of honest optimism, not of deceit.

Among those facts that make Defendants' the more compelling interpretation are that:

- Based on the data obtained in earlier-phase trials of Qnexa, VIVUS spent tens of millions of dollars on pivotal Phase 3 clinical trials, involving thousands of patients as part of an effort to demonstrate the safety and efficacy of Qnexa;
- Qnexa's year-long Phase 3 clinical trial results showed dramatic weight loss and improvements in weight-related co-morbidities to a degree far beyond the thresholds established to show the drug's efficacy;
- Qnexa is composed of two drugs that have long been approved by the FDA and have been used, at much higher dosing levels, for decades by millions of patients;
- while dose-related side effects were observed in the Phase 3 trials, no issues were observed that were (a) outside the labels for Qnexa's component drugs; or (b) more severe than expected from the components;
- while phentermine had been associated with the problematic "phen-fen" combination, evidence had shown the issues to be with the "fen" side of that combination; and
- there exists a strong market demand for a safe, efficacious drug to treat obesity.

Against this backdrop, a "collective" view of Plaintiff's vague allegations does not approach a cogent and compelling inference of scienter, and certainly not one that is more plausible than that Defendants genuinely believed in the promise of this drug. The "omissions" Plaintiff has alleged – additional data on mild depression or cognitive effects; additional, consistent analysis of the disclosed slight increase in heart rate; potential longer-term side effects related to Qnexa's component drugs – do nothing to change the big picture, to undercut Defendants' justifiable optimism, or to explain why Defendants would have engaged in the reprehensible conduct Plaintiffs posit. *See* Mot. at 26; *AstraZeneca*, 559 F. Supp. 2d at 470 (presence of side effects that may affect a drug candidate's risk-benefit analysis does *not* show fraud where management

released positive reports that were believed true or showed no reckless disregard for the truth).

Plaintiff's scienter allegations are based on (a) unsubstantiated assertions attributed to unidentified Confidential Witnesses ("CWs"), and (b) conclusory allegations about Defendants' motives extrapolated from routine corporate objectives and non-discretionary stock trades. The allegations are unchanged from Plaintiff's prior pleading, (*compare* ¶¶ 242-96 *with* AC ¶¶ 148 - 89); and his arguments in opposition to our motion are substantively identical to the prior round of briefing as well. *Compare* Opp. at 19-29 *with* Prior Opp. at 19-28. So are our responses. His CW's were in no position to know anything meaningful, and nothing of any moment is attributed to them anyway. Prior Reply at 17-19; *see also Applestein v. Medivation, Inc.*, 2012 WL 986276 (N.D. Cal. Mar. 22, 2012) (dismissing with prejudice claims based on unreliable and uncorroborated CW statements). The only potentially relevant stock sales he alleges were Mr. Wilson's, all of which were non-discretionary and executed under a Rule 10b-5-1 plan that was in place six months before the class period began. Prior Reply at 19-20. As we have detailed now multiple times, none of Plaintiff's scienter points – separately or collectively – supports any inference of scienter. Mot. at 25-30; Prior Mot. at 25-30; Prior Reply at 16-20.

Even if Plaintiff's wafer-thin CW and motive allegations could somehow be seen to support a scienter inference, it remains Plaintiff's burden to show that the inference is both cogent and compelling, and as plausible as the non-culpable inference that Defendants' optimism was honest. On the record as it stood *before* February 22, 2012, it was certainly plausible that Defendants genuinely believed that Qnexa's safety profile supported FDA approval, particularly when combined with the drug's undisputed efficacy in combatting one of America's most serious public health problems. Indeed, with a split Advisory Committee vote that included a substantial minority of recognized, independent experts supporting approval, it is difficult to characterize Defendants' belief in Qnexa's prospects as *im*plausible. Certainly nothing Plaintiff has alleged undermines that notion, especially to the point that their assertion of fraud is more compelling.

Were there any doubt as to this outcome, the doubt cannot survive the February 2012 Committee meeting, where a near-unanimous panel voted to recommend approval of Qnexa. The vote came after the FDA independently determined that data from a year-long extension of the

pivotal Phase 3 trials confirmed the safety profile for Qnexa that VIVUS had put forward a year earlier. (It also reconfirmed the drug's efficacy over the longer-term.) It took some additional time, but the news from the second year of trial data was that there was no news. The safety data was remarkable in its consistency and its confirmation of the data that had led Defendants to express their optimism in the first place. This time around, with confirmatory data to allay hypothetical concerns expressed by some in July 2010, the vote followed, with many of the same experts who had previously opted for caution and more data voting now to recommend approval. *See supra* Part II. Given the safety data that supported the new NDA and Committee vote and its consistency with the original data, the more plausible explanation of events is the non-culpable inference of Defendants' genuine belief in Qnexa's prospects. Plaintiff has offered nothing that comes close to a more cogent and compelling explanation, and this shortcoming also mandates dismissal of the New Complaint.

IV. CONCLUSION

For the foregoing reasons and those discussed in Defendants' opening papers, the New Complaint should be dismissed. Because Plaintiff has already been afforded the opportunity to cure his deficient pleading and has failed to do, the dismissal should be with prejudice.

Dated: March 30, 2012

HOGAN LOVELLS US LLP

By: */s/ Michael L. Charlson*
Michael L. Charlson

Attorneys for Defendants
VIVUS, INC., LELAND F. WILSON, and
WESLEY W. DAY, Ph.D.